

NOV 09 2001

Covance 7209-105

VALIDATION RESULTS FOR METHOD ACNE					
		MEAN	RELATIVE STD. DEV. (%)	RANGE	SEE (conc)
ANALYTE	Acetonitrile				
MATRIX	Exhalate				
DATE	7-Sep				
LLOQ	6.07 µg/mL	5.83	5.43 - 6.41	0.145	
STANDARD ERROR OF ESTIMATE OF QC SAMPLES (concentration units) (SEE = S.D./SQRT (# of determinations))					
Representative	High QC 60.0µg/mL Med QC 30.0µg/mL Low QC 0.15.0µg/mL	5.72 8.40 4.82	50.0 - 58.7 21.8 - 30.0 13.0 - 15.2		
DESCRIPTIVE INFORMATION ON INSTRUMENT RESPONSE					
Function (Linear, Quadratic, etc.) (Representative)	Linear (1/X weighting)				
Slope	2549				
Intercept	1556				
Other (R)	0.99943				
RECOVERY (as a %)					
High QC in (matrix)=	60.0µg/mL	90.1	5.72	83.3 - 97.8	1.38
Med QC in (matrix)=	30.0µg/mL	89.2	8.41	72.7 - 100	2.00
Low QC in (matrix)=	15.0µg/mL	93.8	4.81	86.7 - 101	1.21
Results with different sample amounts (results of QC evaluations) Intra-assay Representative					
LLOQ QC=	7.50µg/mL	6.07	5.83	5.43 - 6.41	0.145
Low QC=	15.0µg/mL	14.1	5.04	13.1 - 15.1	0.290
Med QC=	30.0µg/mL	27.0	8.19	23.6 - 30.1	0.902
High QC=	60.0µg/mL	53.5	5.08	54.3 - 94.3	1.11
Results with different sample amounts (results of QC evaluations) inter-assay Representative					
LLOQ QC=	7.50µg/mL	6.07	5.83	5.43 - 6.41	0.145
Low QC=	15.0µg/mL	14.1	4.82	13.0 - 15.2	0.182
Med QC=	30.0µg/mL	26.8	8.40	21.8 - 30.0	0.601
High QC=	60.0µg/mL	54.0	5.72	50.0 - 58.7	0.826
STABILITY (assuming any degradation is linear):					
a) Room Temperature in Matrix (+/- %/24 hrs)	60.0µg/mL	93.0			
b) Freeze/thaw (+/- % /3 cycles)	60.0µg/mL	103			
c) Injector (+/- %/24 hrs)	60.0µg/mL	97.2			

Exhalate Summary
9:40 AM 11/12/01Analyst: _____
Reviewed By: _____

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